UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EVY GRU, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AXSOME THERAPEUTICS, INC., HERRIOT TABUTEAU, NICK PIZZIE, MARK JACOBSON, CEDRIC O'GORMAN, and KEVIN LALIBERTE, Defendants.	Case No.: 1:22-cv-3925-LGS

LEAD PLAINTIFF'S SURREPLY IN
OPPOSITIONTO DEFENDANTS' MOTION TO DISMISS
THE AMENDED CLASS ACTION COMPLAINT

Lead Plaintiff Evy Gru ("Plaintiff") respectfully submits this Sur-reply in response to Defendants' Reply in Support of their Motion to Dismiss.[1]

I. PLAINTIFF ADEQUATELY ALLEGES LOSS CAUSATION[2]

A complaint adequately alleges loss causation either through correction, revealing the ***subject*** of misstatements, or through the materialization of a risk concealed, either or both causing loss. (Opp. 24-25). Axsome's November 5, 2020, partial correction, delaying submission of its NDA for AXS-07, ¶¶190-91, caused loss—a 7% stock price decline.[3]

Axsome delayed submission of the NDA "to allow for inclusion of supplemental manufacturing information," ¶190, part of a series of events resulting from manufacturing problems for AXS-07 that Defendants misrepresented throughout the Class Period. On November 5, Defendants acknowledged that the manufacturing of "additional batches" caused the delay. ¶82. During Axsome's next quarterly update, it again delayed submitting the NDA, claiming it was "waiting on one vendor report," and did not end up submitting the NDA until June 2021. ¶¶50, 78. These delays coincide precisely with CW1's description of a delay in a trial for AXS-07 that was originally scheduled to start in April 2021, because the manufacturer was not able to make the drug. ¶¶67-75. This study was still delayed when CW1 left Axsome in February 2022. ¶¶72-74. The FDA then rejected the NDA less than two months later because of "the need for additional CMC data" related to the "manufacturing process," after Axsome failed to resolve problems that

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[1] "¶__" references are to the Amended Class Action Complaint ("Complaint," ECF No. 37). Plaintiff's Opposition (ECF No. 46) is "(Opp. __)." Defendants' Reply Memorandum (ECF No. 52) is "(Reply __)."

[2] Defendants' failure to raise their November 5 loss causation argument in their Motion waives it. *Double Line Capital LP v. Odebrecht Finance, Ltd.*, 323 F. Supp. 3d 393, 450 (S.D.N.Y. 2018). Arguing that attacking the November 5 correction would not have been "case dispositive" (Reply 3, n.4) is wrong. Prevailing as to the April 25 correction alone ***would not have been dispositive*** since the November 5 partial correction remains. Defendants' logical stumble cannot excuse their failure to argue that the November 5 disclosure did not cause loss.

[3] Rule 8(a)'s notice pleading standard applies to the Complaint's loss causation allegations. If the allegations are plausible, they suffice. *In re Omega Healthcare Investors, Inc. Sec. Litig.*, 563 F. Supp. 3d 259, 266, n.7 (S.D.N.Y. 2021) ("vast majority of courts in this district" apply Rule 8(a) to loss causation pleading) (citations omitted).

the FDA raised. ¶¶53, 56, 58. Plaintiff is entitled to the reasonable inference that the manufacturing problems CW1 identified were of the same kind as those Defendants disclosed on November 5.[4]

Defendants argue that the November 5 disclosure cannot be both corrective and "itself a misrepresentation." (Reply 3-4). But partial corrective disclosures, by their very nature, perpetuate fraud, revealing a part, but not all, of the truth. *See Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 202-03 (S.D.N.Y. 2010) (holding series of partial disclosures that continued to mislead can reveal truth) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342 (2005)).[5] Axsome's November 5 delay both revealed the subject of Defendants' prior misstatements and constituted a materialization of a risk they concealed. *See Cohen v. Kitov Pharm. Holds., Ltd.*, 2018 WL 1406619 (S.D.N.Y Mar. 20, 2018) (Schofield, J.) (holding it "does not alter the basic loss-causation calculus" whether the truth was revealed through a corrective disclosure or "events constructively disclosing the fraud" (quoting *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 262 (2d Cir. 2016)). Defendants disclosed that manufacturing issues delayed the NDA but continued to mislead, failing to disclose the truth: Axsome could not manufacture sufficient quantities of AXS-07 even for clinical trials. ¶¶48, 82-83.

II. THE COMPLAINT PLEADS SCIENTER PRIOR TO NOVEMBER 5, 2020

The Complaint adequately alleges scienter before the November 5, 2020 partial correction. While the FDA inspection report arose out of an inspection in June 2021, each of the Individual

[4] *See IWA Forest Indus. Pension Plan v. Textron, Inc.*, 14 F.4th 141, 145-47 (2d Cir. 2021) (reversing dismissal for failing to draw reasonable inference in plaintiff's favor).

[5] Defendants' cases (Reply at 3-4) are inapposite, dealing with "disclosures [that] did not reveal the pertinent truth." *In re MiMedx Grp., Inc. Sec. Litig.*, 2021 WL 7210372, at *3 (N.D. Ga. Mar. 25, 2021); *see also In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 574 F.3d 29, 41 (2d Cir. 2009) (holding "industry events" showing "***other companies***" not doing well did not reveal "the truth about Flag[]"); *In re Rhodia S.A. Sec. Litig.*, 531 F. Supp. 2d 527, 546 (S.D.N.Y. 2007) (holding "a 'sharp drop' resulting from the announcement of . . . a particular incident" supports loss causation). Other cases that Defendants cite (Reply at 3) dealt with plaintiffs that sold their shares before even a partial corrective disclosure. *See, e.g.*, *Schuler v. NIVS Intellimedia Tech. Grp.*, 2013 WL 944777, at *10-11 (S.D.N.Y. Mar. 12, 2013); *In re Velti PLC Sec. Litig.*, 2015 WL 5736589, at *29 (N.D. Cal. Oct. 1, 2015); *see also Wilamowsky v. Take-Two Interactive Software, Inc.*, 818 F. Supp. 2d 744, 753 (S.D.N.Y. 2011) (addressing short seller)).

Defendants other than Laliberte served in the same roles at that time as they did at beginning of the Class Period. ¶¶18-22. Moreover, CW1 and CW3 both worked at Axsome from before the start of the Class Period and described its senior executives' practices without any temporal limitation. ¶¶67, 87, 214-15. It is at least equally compelling that Defendants other than Laliberte recklessly disregarded the CMC issues and their impact on the NDA filings prior to November 5.[6] *See Yannes v. SCWorx Corp*., 2021 WL 2555437 (S.D.N.Y. June 21, 2021) (denying dismissal, finding that later data can confirm what defendants should have previously known).

Defendants' discussion of the cases cited in Plaintiff's Opposition (*see* Reply 9-10) ignores the consistent rulings sustaining securities claims against pharmaceutical companies raising allegations similar to those here, where defendants misrepresented CMC issues that caused the company to delay submission of an NDA or increased the risk that the FDA would reject the application. The most that Defendants can argue is that their alternative inference "is just as likely" as the culpable inference that Plaintiff alleges. (*Id.* at 9). That contention ***supports Plaintiff*** because scienter allegations suffice where the inference is "cogent and ***at least as compelling*** as any opposing inference." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-24 (2007).

III. THE COMPLAINT ADEQUATELY ALLEGES FALSITY

Defendants' falsity arguments fail as to the pre-November 5 time period. *First*, the uninterrupted series of events described above shows that Axsome's inability to manufacture AXS-07 caused the delay Defendants announced on November 5. This issue predated November 2020, because Axsome had prepared for the AXS-07 NDA since the start of the Class Period and the manufacturing of a complex drug is not dealt with in a single day. ¶¶59-61, 63, 80, 109-11.

Second, Axsome's completion of Phase 3 trials ***earlier in the Class Period*** (Reply at 11)

[6] Tabuteau and Jacobson also discussed AXS-07's manufacturing in detail on November 5, 2020. ¶¶82-83, 148-50, 200-01. Defendants admit statements "evinc[ing] familiarity with the data" contribute to scienter. (Reply 10, n.18).

does not mean that Axsome continued to be able to manufacture AXS-07 as it prepared its NDA, that Axsome was ever able to produce AXS-07 at commercial scale, or that the supply used for those earlier trials was not produced well before they were completed. *See* ¶¶39, 44, 46. Plaintiff does not allege that Axsome did not produce any AXS-07 in the past, but rather, that its current supply was nearing expiration and it could not manufacture any ***new batches*** of the drug. ¶70.

Third, Tabuteau admitted Axsome used the same CMO to manufacture AXS-07 for trials and commercial purposes. ¶133. Axsome's inability to manufacture AXS-07 for the study that CW1 described thus meant that it also could not make the drug for commercial use or other trials.

IV. PLAINTIFF CAN REPRESENT THE ENTIRE CLASS

Plaintiff may bring claims for the entire Class Period, not just those related to the November 5 partial corrective disclosure. *See In re NTL, Inc. Sec. Litig.*, 2006 WL 330113, at *9-11 (S.D.N.Y. Feb. 14, 2006) (certifying class, finding typical a plaintiff who sold before the final corrective disclosure). This rule is particularly applicable here because the whole Complaint relates to the same series of events concerning Axsome's inability to manufacture AXS-07. *See In re Symbol Tech., Inc. Sec. Litig.*, 2015 WL 3915477 *4 (E.D.N.Y. June 25, 2015) (finding typicality in case alleging partial disclosures related to "single overarching" scheme).[7]

In any event, if the Court dismisses the claims related to the November 5 disclosure, additional plaintiffs will have the opportunity to intervene to preserve the remaining claims on behalf of the proposed Class. *In re Avon Sec. Litig.*, 1998 WL 834366 *2 (S.D.N.Y. Nov. 30, 1998) (certifying class after original representative withdrew and court allowed substitution of class representative); *In re Arakis Energy Corp. Sec. Litig.*, 1999 WL 1021819, at *6, 13 (E.D.N.Y. Apr. 27, 1999) (intervention is appropriate where it neither alters claims nor results in undue delay).

[7] The only case that Defendants cite (Reply 5 n.8) did not raise any "actionable claims regarding statements made before their purchase." *Plumber & Steam. Loc. 773 Pens. Fund v. Danske Bank A/S*, 11 F.4th 90, 104 (2d Cir. 2021).

For these reasons, and those in the Opposition, the Court should deny Defendants' Motion.

Dated: February 7, 2023

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